DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 24, 2015

Smith & Nephew, Incorporated
Mr. Jeff Sprague
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K143096
Trade/Device Name: SL-PLUS™ MIA Femoral Stem with Ti/HA and SL-PLUS™ Femoral Stem with Ti/HA
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, KWY, LWJ
Dated: February 19, 2015
Received: February 20, 2015

Dear Mr. Sprague:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Smith & Nephew SL-PLUS® MIA and SL-PLUS Femoral Stem with Ti/HA

510(k) Number (if known): K143096

Device Name: SL-PLUS® MIA Femoral Stem with Ti/HA

Indications for Use:

The SL-PLUS® MIA Stem and the SL-PLUS® MIA Stem with Ti/HA (INTEGRATION-PLUS®) is indicated for:

Indications Standard Stem
The SL-PLUS MIA Hip Stem is indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Indications Lateral Stem
The SL-PLUS MIA Laterialzed stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute)

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

INDICATIONS FOR USE

Smith & Nephew SL-PLUS® MIA and SL-PLUS Femoral Stem with Ti/HA

510(k) Number (if known): K143096

Device Name: SL-PLUS® Femoral Stem with Ti/HA

Indications for Use:

The SL-PLUS® Stem and the SL-PLUS® Stem with Ti/HA (INTEGRATION-PLUS®) is indicated for:

Indications Standard Stem
The SL-PLUS Stem is intended for advanced hip joint wear due to degenerative, post-traumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head

Indications Lateral Stem
The SL-PLUS Laterialzed stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute)

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Smith & Nephew SL-PLUS™ MIA and SL-PLUS Femoral Stem with Ti/HA

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	October 27, 2014
Contact Person	Jeff Sprague, Regulatory Affairs T (901) 399-5215 F (901) 721-2736
Name of Device:	SL-PLUS™ MIA and SL-PLUS Standard and Lateral Femoral Stem with Ti/HA
Common Name:	Total Hip Joint, Femoral Component, Cementless
Device Classification Name and Reference:	21 CFR 888.3353 –Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3390 – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LZO, KWY, LWJ

Device Description

The SL-PLUS™ MIA Femoral Stem with Ti/HA coated by Medicoat AG is identical to the coated design of the SL-PLUS™ MIA Femoral Stem cleared via K122296. The subject stems are made from forged titanium alloy, Ti-6Al-7Nb, with a double coating (triple layer): titanium plasma sprayed coating (two layers) with an additional thin layer of hydroxyapatite. The Ti/HA coating form Medicoat AG is substantially equivalent to the Ti/HA coating on the SL-PLUS™ MIA Standard and Lateral Femoral Stems with Ti/HA cleared via premarket notification K122296.

The SL-PLUS™ Femoral Stem with Ti/HA coated by Medicoat AG is identical to the coated design of the SL-PLUS™ Femoral Stem cleared via K120211. The subject stems are made from forged titanium alloy, Ti-6Al-7Nb, with a double coating (triple layer): titanium plasma sprayed coating (two layers) with an additional thin layer of hydroxyapatite. The Ti/HA coating form Medicoat

AG is substantially equivalent to the Ti/HA coating on the SL-PLUS™ Standard and Lateral Femoral Stems with Ti/HA cleared via premarket notification K120211.

Intended Use

SL-PLUS MIA

The SL-PLUS™ MIA Stem and the SL-PLUS™ MIA Stem with Ti/HA (INTEGRATION-PLUS™) is indicated for:

Indications Standard Stem

The SL-PLUS MIA Hip Stem is indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Indications Lateral Stem

The SL-PLUS MIA Laterialzed stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute)

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

SL-PLUS

The SL-PLUS™ Stem and the SL-PLUS™ Stem with Ti/HA (INTEGRATION-PLUS™) is indicated for:

Indications Standard Stem

The SL-PLUS Stem is intended for advanced hip joint wear due to degenerative, post-traumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head

Indications Lateral Stem

The SL-PLUS Laterialzed stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute)

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended

drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

The above indications are substantially equivalent to the indications cleared previously for the SL-PLUS MIA Standard and Lateral Femoral Stem with Ti/HA (K122296) and the SL-PLUS Standard and Lateral Femoral Stem with Ti/HA (K120211).

Technological Characteristics

A review of the mechanical data indicates that the SL-PLUS™ MIA and SL-PLUS Femoral Stem with Ti/HA is capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information

The overall design, materials, and indications for use for the SL-PLUS™ MIA and SL-PLUS Femoral Stem with Ti/HA are substantially equivalent to the following commercially available predicate devices.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew Orthopaedics AG	SL-PLUS™ MIA Standard and Lateral Femoral Stems with Ti/HA	K122296	9/28/2012
Smith & Nephew Orthopaedics AG	SL-PLUS™ Standard and Lateral Femoral Stems with Ti/HA	K120211	7/19/2012

The following tests were used as a basis for the determination of substantial equivalence:

- HA powder and coating characterization

All tests which are in relation to the surface characterization (physical, chemical or mechanical) are discussed in detail in the Ti/HA Coating Master File **MAF – 2541** and are not included in this 510(k).

Conclusion

As previously noted, this 510(k) Premarket Notification is being submitted to request clearance for the SL-PLUS™ MIA Femoral Stem with Ti/HA and SL-PLUS™ Femoral Stem with Ti/HA coated by Medicoat AG. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the commercially available predicate devices listed above.